



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,331	01/18/2002	Akiyo Yamada	31512-176817	5969

26694 7590 03/28/2005

VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
----------	--------------

1638

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,331

Applicant(s)

YAMADA ET AL

Examiner

Medina A Ibrahim

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 13-66, 70-110, 114-117, 119-122 and 125 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 13-63, 70-110, 119 and 120 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-66, 114-117, 121-122 and 125 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 12/16/04 in reply to the Office action of 09/16/04 has been entered. Claims 8-12, 67-69, 111-113, 118, and 123-124 have been cancelled. Therefore, claims 1-7, 13-66, 70-110, 114-117, 119-122, and 125 are pending.

This application contains claims 1-7, 13-63, 70-110, and 119-120 drawn to an invention nonelected with traverse in the response of 07/04/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 64-66, 114-117, 121-122 and 125 are under consideration. Claims 64-66, 121-122 and 125 have been amended.

Claim Objections

Claims 64-65 remain objected to for containing more than one period, as stated in the last Office action of 09/16/04. "Seq. ID No." should be replaced with ---SEQ ID NO: ---. Applicant has neither amended nor argued against this objection.

At claims 115-116, "host" should be inserted before "cell" for clarification, as stated in the last Office action of 09/16/04. Applicant has neither amended nor argued against this objection.

Specification

The disclosure remains objected to because of the following informalities: pages 6-17 refer to the specific claims. The specification cannot refer to specific claims. In the

Art Unit: 1638

response of 12/16/04, Applicant deletes the claims but not the numbers of these claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 66, 114-117, 121-122, and 125 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 66 is indefinite in the recitation of "using" a washing buffer without any active, positive method steps delimiting how this use is actually practiced. Also, "using" and "washing" appear redundant. Dependent claims 114-117, 121, 122, and 125 are included in the rejection. It is suggested that "using" be changed to ---with---.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 64-66, 114-117, 121-122, and 125 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated DNA of SEQ ID NO: 1 encoding a protein that confers tolerance against salt stress, a vector and transgenic plant comprising said DNA, and a method of transforming plant/plant cell with said vector, does not reasonably provide enablement for the isolated DNA of SEQ ID NO: 39 or a part thereof and hybridizing DNA sequences thereof, a DNA encoding

Art Unit: 1638

SEQ ID NO: 40 or a modified protein thereof having the activity of improving salt stress tolerance, a vector, transgenic plant/plant cell comprising said DNA, and a method of transforming a host cell with said vector. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Office action of 09/16/04. Applicant's arguments filed 12/16/04 have been considered but are not deemed persuasive.

Applicant argues that SEQ ID NO: 39 encodes a protein having salt stress tolerance activity and Applicant provides reference Figures 1 and 2 showing *E.coli* cell transformed with SEQ ID NO: 39 encoding SEQ ID NO: 40, wherein the transformed *E.coli* exhibits improved salt tolerance as compared to the control cell (response, pp. 33-34).

This is not persuasive because the rejected claims are not limited to SEQ ID NO: 39 encoding SEQ ID NO: 40 conferring salt stress tolerance to *E.coli* cells. The claims are broadly drawn to SEQ ID NO: 39, or a part and hybridizing DNA thereof encoding SEQ ID NO: 40 or a modified protein thereof having the activity of improving salt stress tolerance in a transgenic plant. Applicant has not taught expression of SEQ ID NO: 39 in a transgenic plant, and the phenotypic effect cannot be predicted based on the effect of said DNA in *E.coli* cells. The phenotypic characteristics that will result from expression of a given DNA cannot be reliably predicted. The state of the art as evidenced by Applicant's specification (paragraph bridging pages 2 and 3) is that the

Art Unit: 1638

mechanism of drought tolerance in plants at the genetic level is unknown. The specification, page 4, lines 4-6, also states that it has never been reported to improve the level of salt stress tolerance of higher plants by introducing proteins whose sequences of amino acids are modified (improved) and whose activity improves salt stress tolerance". Therefore, Applicant has provided no evidence to support the conclusion that expression of SEQ ID NO: 39 in a transgenic plant will improve salt stress tolerance in the transgenic plant. Given the lack of guidance and specific examples commensurate in scope with the breadth of the claimed polynucleotide; given the unpredictability in the art in the transformation of a plant for a specific phenotype; and the state of the art with respect to salt stress tolerance in plants, it is reasonable to conclude that undue experimentation would be required to practice the invention throughout the broad scope of the claims.

Applicant has not specifically argued against the rejection to a part of SEQ ID NO: 39 or its complementary, DNA that hybridizes thereto encoding a protein having salt tolerance activity, and a DNA encoding protein with one or more modified amino acids relative to SEQ ID NO: 40 and still retaining salt tolerance activity. Therefore, the rejection to claims drawn to said DNA, vector and transgenic plant/cell comprising said DNA, and a method of transforming host cells with said DNA is also maintained.

Written Description

Claims 64-66, 114-117, 121-122, and 125 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a

Art Unit: 1638

way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 09/16/04.

Applicant's arguments filed 12/16/04 have been considered but are not deemed persuasive.

Applicant argues the claimed invention is adequately described because SEQ ID NO: 39 has been shown to encode a protein having salt tolerance activity when expressed in *E.coli* cells. Applicant provides reference figures 1 and 2 showing *E.coli* cell transformed with SEQ ID NO: 39 encoding SEQ ID NO: 40, wherein the transformed *E.coli* exhibits improved salt tolerance as compared to control cell (response, pp.33-34).

This is not found persuasive because the rejected claims are not limited to SEQ ID NO: 39 encoding SEQ ID NO: 40 and its expression in *E.coli* cell, but are broadly drawn to non-described "parts" of any size and length and hybridizing DNA sequences of SEQ ID NO: 39, and DNA sequences encoding proteins with multiple amino acid modifications. Applicant has not described a transgenic plant expressing SEQ ID NO: 39 as encompassed by the claims. Applicant has not specifically argued against the rejection to broad claims encompassing modified DNA and protein, transgenic plant, and method claims using said DNA. Also, Applicant has not described a representative number of DNA of the genus claimed. Therefore, given the vast of DNA sequences encompassed by the claims; the substantial variation in structures and function among DNA sequences comprising any "part" of SEQ ID NO: 39 and DNA sequences encoding

Art Unit: 1638

proteins with one or more modified amino acids relative to SEQ ID NO: 40; and the lack of description of transgenic plant expressing SEQ ID NO: 39, it is reasonable to conclude that Applicant was not in possession of the invention as broadly claimed at the time the application was filed. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102/103

Claims 64-66, 114-117, 121-120, and 125 remain rejected under 35 U.S.C. 102(b) as being anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sheveleva et al (Plant Physiology (1997), vol. 115, pp. 1211-1219; Applicant's IDS). Note, the claims recite " a part" of SEQ ID NO: 39, and DNA encoding proteins with multiple of amino acid modifications and hybridizing sequences thereof. This rejection is repeated for the reasons of record as set forth in the last Office action of 09/16/04. Applicant has not argued against this rejection. Therefore, the rejection is maintained.

Claims 64-66, 114-117, 121-120, and 125 remain rejected under 35 U.S.C. 102(b) as being anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious over Xu et al (Plant Physiology (1996) 110:249-257, Applicant's IDS). Note, the claims recite " a part" of SEQ ID NO: 39, and DNA encoding proteins with multiple of amino acid modifications and hybridizing sequences thereof. This rejection is repeated for the reasons of record as set forth in the last Office action of 09/16/04. Applicant has not argued against this rejection. Therefore, the rejection is maintained.

Art Unit: 1638

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Remarks

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

Application/Control Number: 10/031,331

Page 9

Art Unit: 1638

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/11/05

Mai

A handwritten signature in black ink, appearing to read "Amy Nelson", with a stylized flourish at the end.

AMY J. NELSON, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600